

Design and Rationale of a Comparative Effectiveness Study to Evaluate Two Acupuncture Methods for the Treatment of Headaches Associated with Traumatic Brain Injury

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ABSTRACT

Background: Exposure to deployment and battle can induce a constellation of physical, cognitive, psychological, and behavioral symptoms, also referred to as war-related Trauma Spectrum Response (wrTSR). One prevalent cause of this response is traumatic brain injury (TBI) and its ensuing sequelae, such as pain and suffering caused by post-traumatic headache. Current pharmacologic treatment of these headaches is often inadequate and complicated by the multi-component nature of wrTSR. Acupuncture has been found to reduce pain, improve health-related quality of life, prevent migraine headaches, and reduce tension-type and chronic daily headaches.

Objective: An ongoing study is endeavoring to advance understanding of the speed and depth of healing induced by two acupuncture approaches, compared to current standard practice and with the aim of providing insights to guide future implementation of acupuncture treatment in the military.

Design: A comparative effectiveness study protocol will be used to determine if auricular acupuncture (AA) or semi-standardized traditional Chinese acupuncture (TCA) alleviates headaches and reduces associated comorbidities more effectively than usual care alone in a cohort of active duty military personnel with mild-to-moderate TBI.

Summary: Given that the study is currently underway, no results or conclusions can be reported at present. While current evidence from acupuncture research demonstrates its promising healing impact across the wrTSR, a number of unanswered questions and information gaps remain. It is hoped that the proposed study will address some of these questions and gaps.

Key Words: Acupuncture, TBI, Headaches, Military, Trauma Spectrum Response

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INTRODUCTION

SINCE WORLD WAR I, clear clusters of physical and psychological symptoms occurring as a result of exposure to intense combat have been identified (e.g., hysteria, shell shock, polytrauma); the stress of combat is notoriously pathogenic.^{1,2} Indeed, the conflicts in Afghanistan (Operation Enduring Freedom or OEF) and Iraq (Operation Iraqi Freedom or OIF) are associated with high rates of stress-symptom endorsement, post-traumatic stress disorder (PTSD), and utilization of military mental health services.^{3,4} With nearly 1.8 million U.S. veterans having served in OEF or OIF, these conflicts represent the most sustained combat operations for U.S. forces since the Vietnam War. Current research on this population of active duty personnel suggests the creation of a new generation of veterans at risk for the range of chronic mental health problems that result from the sustained hardship, sacrifice, and war zone trauma.^{3,4}

Impact of Combat and Deployment-Related Stress

Thousands of wounded warfighters are returning with both psychological and physical injuries after exposure to combat trauma, many with long-term symptomatic and functional consequences.^{3,5} In fact, previous research conducted after military conflicts has shown that deployment and exposure to combat result in increased risk of psychiatric and physical illnesses, including traumatic brain injury (TBI), acute stress disorder, PTSD, major depression, and substance abuse, in addition to reduced quality of life (QoL), functional impairment in social and employment settings, and increased use of health services.

Head and neck injuries are common in combat, occurring in 15%–20% of all battle injuries.^{6,7} In fact, rates of post-concussive symptoms (PCS), especially headache, may occur more frequently than in civilian populations.^{8,9} Chronic, persistent, or recurrent headaches are of particular concern among patients with mild TBI (mTBI), which afflicts up to 28% of all deployed warfighters.^{6,7} Treatment of these headaches with analgesics and narcotics are often inadequate, require persistent drug use, and may potentially lead to drug intolerance and dependence. Further complicating headache treatment of mTBI patients is the multitude of comorbid physical, cognitive, and psychological symptoms that may also be present in these individuals.

Comorbidity of Injuries

Research highlights the multicomponent and overlapping nature of traumatic combat injuries; not only are soldiers at risk for returning with physical and/or emotional symptoms, but these veterans are also at risk for developing more than one problem. In fact, chronic pain, PTSD, cognitive deficits, and neuropsychiatric conditions are often comorbid in these patients.^{10,11} For instance, psychiatric conditions (e.g., depression, anxiety) may co-occur with chronic pain, height-

ened stress-reactivity, and PTSD in 24%–66% of combat-wounded OIF/OEF veterans;^{12,13} 60% of these soldiers, moreover, either have some form of brain injury or present with cognitive, emotional, and behavioral problems resulting from neural insult.¹² Furthermore, mTBI often involves a spectrum of physical (i.e., headache, dizziness, balance, visual changes, pain), cognitive (i.e., memory, attention, concentration), and psychological or behavioral (i.e., depression, anxiety, anger, mood swings, social and family dysfunction) symptoms.¹⁴ PTSD, moreover, often manifests with a similar set of symptoms and dysfunction as mTBI. The literature also suggests that relationships exist among insomnia, major depression, anxiety disorders, substance abuse, suicide, decreased immune functioning, and cardiovascular disease.¹⁵

When induced by exposure to deployment and battle, this constellation of trauma-related manifestations is collectively referred to as war-related Trauma Spectrum Response (wrTSR).^{*} In summary, individuals exposed to environmental and/or psychosocial insults, such as that faced in in-theater combat, can present a core pattern of common symptoms including:

- (1) Psychological and emotional distress (e.g., depression, anxiety, anger)
- (2) Cognitive impairment
- (3) Chronic and often refractory pain of organic and psychosomatic origins
- (4) Drug/opioid desensitization (with abuse potential)
- (5) Somatic (sleep, appetite, sexual, and energy) dysfunction.

Problems with Current Care and the Need to Focus Research on the Whole Person Who Has wrTSR Response

wrTSR is a large and growing clinical problem, with as many as 10,000 service members (SMs) estimated to be suffering from this pattern of comorbidity.¹⁶ While many pharmacological and psychological interventions can be successful, the current standards of care for wrTSR are probably not maximally effective, nor do they fully address the biopsychosocial aspects, full complexity, and overlap of comorbidities characteristic of wrTSR. Triggered by combined mind–body/brain injuries, the various manifestations of wrTSR share many common pathophysiological and recovery mechanisms. As such, treatments should consider the full presentation of wrTSR rather than focusing on individual components, aiming to investigate more multidimensional, integrative, and comprehensive approaches to patient treatment of such total mind–body/brain injuries.

^{*}See Jonas W, Walter J, Fritts M, Niemtzow RC. “Acupuncture for the Trauma Spectrum Response: Scientific Foundations, Challenges to Implementation” in this issue.

There is an imminent need for additional research to define and understand wrTSR more completely so as to develop interventions based on both neuroscientific information and new integrated care models.¹² Such care should address the whole person experience of wrTSR, seek to facilitate prevention and cure, enhance the inherent healing capacities of the injured person, utilize innovative therapeutic approaches based on rigorous methods of empirical evaluation, and narrow the gap between research and clinical practice.^{13,17}

Given that the presence of comorbidities complicates the management of wrTSR and worsens the prognosis for recovery, it seems that integrative medicine approaches may be particularly beneficial for treating soldiers affected by wrTSR. Complementary and integrative medicine (CIM) refers to a family of holistic practices used in conjunction with conventional medicine to address the biological, psychological, social, and spiritual aspects of health and illness. This blending of therapies and services generally exceeds the collective effect of the individual practices¹⁸ and calls for a seamless continuum of decision-making and patient-centered care and support. There are a variety of CIM approaches available to address wrTSR, with some focusing on self-care and self-treatment (e.g., guided imagery,¹⁹ relaxation response,²⁰ mindfulness training,²¹ yoga,²² diet and exercise, device-assisted biofeedback), and others relying on CIM professionals (e.g., acupuncture,^{23,24} Reiki, osteopathic manipulation,²⁵ chiropractic) to administer nondrug and nonpsychiatric treatments to complement conventional treatment and facilitate healing.

Because CIM comprises an array of practices used in conjunction with conventional medicine to enhance health, stimulate recovery, and reduce side-effects, CIM is therefore, by design, more holistic than condition-specific treatments more often found in conventional medicine. Complementary and integrative approaches may be able to address the complex, comorbid nature of wrTSR because not only does CIM allow for a diverse treatment of multiple concomitant symptoms, but this approach also promotes total wellness, healing, and self-management through the integrated interdisciplinary collaboration of medical providers to treat the whole person, rather than fragmented care solely based on organ symptoms and disease conditions.

Acupuncture Research Background

Originating in China, acupuncture has been used as a medical treatment modality for more than 2500 years but has only received attention in the United States relatively recently. Acupuncture theory holds that energy, known as Qi, travels along pathways or meridians within the body, moving in a dynamic and fluid interplay of opposites described as Yin (e.g., quiet, contemplative, and internal); and Yang (e.g., active, assertive, and external).

In a healthy autonomic nervous system, sympathetic nervous system (SNS) arousal (what the Chinese call Yang) and parasympathetic nervous system (PNS) restoration (what the Chinese call Yin) are balanced. Chinese Medicine understands disease to result from dysregulation or imbalance between Yin and Yang, or from a Deficiency or Stagnation of Qi/energy. Thin metal acupuncture needles are inserted at specific points along the meridians to restore balance and regulation between Yin and Yang, enhance Qi/energy, or move obstructed Qi/energy.

Currently, acupuncture is used to treat numerous conditions. As of 1998, it was estimated that more than 1 million people in the United States received 10 million acupuncture treatments.²⁶ Treated disorders include acute and chronic pain of various etiologies, nausea, stress, anxiety, depression, substance abuse, allergic rhinitis, asthma, gastrointestinal disorders, infectious disease, and brain injury from stroke.²⁷

Acupuncture Treatment Efficacy

Current literature shows that acupuncture is most effective for treating postoperative dental pain,^{28,29} postoperative³⁰ and chemotherapy-induced nausea and vomiting,^{28,29,31,32} idiopathic headache, and somatic and postoperative pain,^{33–38} and is promising in the treatment of myofascial pain, tennis elbow, and carpal tunnel syndrome.³⁹ Recent blinded, randomly controlled studies, moreover, support the efficacy of acupuncture for treating pain associated with headache, fibromyalgia, knee arthroscopy,⁴⁰ labor, and other painful conditions in both humans and animals.^{41–43}

Acupuncture has proven to be efficacious for treating a number of conditions, with the potential to reduce trauma spectrum symptomatology in patients with TBI. In fact, not only has acupuncture shown promise for the care and prevention of migraine, tension-type and chronic daily headaches,^{44–46} but also for the treatment of most of the components of wrTSR dysfunctions including insomnia,^{47–53} stress and anxiety,^{54–56} and depression,^{57–64} as well as perceived,⁶⁵ chronic,^{66–68} and acute pain.⁶⁹ In addition, a study by Hollifield and colleagues concluded that, while more research is warranted, acupuncture may be a promising treatment option for PTSD.⁷⁰ Several studies have also found that acupuncture can enhance cognitive and physical functioning in patients who have brain-damage and stroke,^{71,72} and that it may also be effective for treating some neurogenic cognitive disorders (e.g., autism).⁷³ Other studies, moreover, have reported benefit for patients after surgery and head trauma.^{24,74–78} Furthermore, while research results for the effectiveness of acupuncture in drug addiction is mixed, there are national standards for using ear acupuncture for drug addiction with reported effectiveness, and several states mandate a trial of acupuncture for drug addiction.⁷⁹ Indeed, there is substantial evidence that acupuncture may reduce headache and pain as well as induce

recovery across numerous trauma spectrum symptoms in patients with TBI, possibly at a low cost and with little risk of producing side-effects.

DESIGNING THE STUDY

Proposed Mechanisms of Action: Two Approaches

Traditional Chinese Acupuncture (TCA). Acupuncture may have ubiquitous effects, because it appears to influence simultaneously several common, interacting mechanisms involved in trauma response and recovery. Acupuncture is known to have effects on the autonomic nervous system (ANS) and the prefrontal cortex—systems that are involved in the pathophysiology of emotional, pain, and cognitive dysfunctions of wrTSD.^{71,80,81} It has been established that acupuncture stimulates the release of endogenous opioids and that analgesic effects are blocked in a dose–response manner by naloxone, an opioid antagonist.³⁸ Cho et. al. have demonstrated that the cingulate gyrus and the thalamic areas, activated in the presence of applied pain stimulation, show brain activity that correlates with decreased pain sensation in human subjects.⁷² Acupuncture appears to cause a broad matrix of CNS responses involving the amygdala, hippocampus, hypothalamus, cerebellum, basal ganglia, anterior cingulate, insula, and other limbic structures.⁸⁰ Responses by the CNS may be dependent on the type and frequency of acupuncture treatment.^{80,82,83} In this new study, we plan to use a semistandardized form of TCA previously developed and found to be effective for reducing symptoms across multiple comorbidities.⁷⁰

Auricular Acupuncture (AA). Auricular acupuncture is a therapeutic technique in which thin needles are inserted into specific points in the auricle of the external ear to affect health conditions in other parts of the body.⁸³ AA is based on the neurophysiological theory that the ear represents a somatotopic map (i.e., a systematic representation of the anatomical regions of the body) and that stimulation of various points on this map will affect the corresponding anatomical regions.⁸⁴ Advantages of auricular acupuncture methodology are that patients can be treated while fully clothed and certain auricular needles can remain inserted safely for several days.⁸⁵ Furthermore, AA lends itself well to symptomatic protocols that do not require the relatively more-elaborate diagnostic tools of TCA, and thus can be taught to allied health personnel. It has been proposed that auricular acupuncture ameliorates pain by stimulating the release of endogenous opioids,⁸⁶ and activating diffuse noxious inhibitory controls.⁸⁷ Randomized controlled studies have supported AA's effectiveness for relieving a large number of diseases and complaints, including pain and anxiety in patients with cancer,⁸⁸ problems related to knee

arthroscopy⁴⁰ and hip arthroplasty,⁴³ postoperative pain,^{40,43} chronic low-back pain,⁸⁹ problems related to spinal-cord injury, and pain in other acute care settings.^{23,90}

Placebo or Comparative Effectiveness Research (CER)?

In developing this study, extensive discussion occurred with scientists and military leaders on whether to conduct a placebo-controlled trial or to compare directly two types of acupuncture with usual care (UC) in wrTSR. The agreement reached was to do a comparative effectiveness study. There were many reasons for this. First, CER provides more direct evidence for the best approach to conditions as used in practice; AA, TCA, and UC are three approaches already in use for wrTSR in the military. Second, the Institute of Medicine report on CER recommended direct comparison of acupuncture to other forms of treatments for pain and related symptoms.⁹¹ Third, recent research on acupuncture demonstrates that the placebo component of acupuncture is probably complex and multiple.⁹² Designing a proper-placebo controlled trial poses many methodological and ethical complexities that would interfere with the ability to answer the more-pragmatic questions. Finally, the bottom line for the military is to identify safe and effective treatments that can be implemented on a widespread basis within the current military infrastructure. Thus, information on feasibility, dose, delivery, costs, and veracity are equal to effectiveness and more important than efficacy. For these and other reasons, a three-armed CER design was developed to answer these questions.

Comparative Effectiveness of Three Approaches: Rationale and Hypotheses

Because acupuncture elicits a “multimechanism” whole-person response, acupuncture could potentially be advantageous for treating the multisymptom complex of wrTSR. Because TCA and AA differ in their approach to diagnosis and treatment, this study will seek to evaluate the comparative effectiveness of these approaches on headache and comorbid symptoms associated with mild-to-moderate TBI in active duty military personnel. The overall objectives are to obtain preliminary estimates and to determine whether either acupuncture method is more effective than usual care for (1) improving headache-related QoL, (2) decreasing headache frequency and severity, and (3) reducing comorbid symptoms associated with mTBI.

The semi-individualized TCA procedure has three components: First, it evaluates the nature of the headache symptomatology according to 12 distinct patterns described by TCA, based on the expected injuries sustained and the environmental conditions of Iraq and Afghanistan. Second, because Chinese Medicine rests on the thesis that preventing disease and maintaining health is based on ensuring the vitality, balance, and harmony of the person's underlying

constitution, and not simply the elimination of symptoms, the patient's underlying constitution or personality/character type is determined. Third, Ah-Shi points, or points of local tenderness, on the head are located.

TCA asserts that treating the constitution will support symptom-based treatment, lessen a patient's predisposition to suffer future similar problems, and make a positive impact on several comorbid symptoms in this population (e.g., insomnia, digestive upset, anxiety).

Conversely, the AA protocol is a standardized algorithm that treats all headaches similarly, regardless of diagnostic pattern or underlying constitutional type. This symptom-driven approach does not have the TCA benefit of an individualized assessment that treats distinct headache pattern(s) and underlying constitutional vitality in that AA specifically targets the symptom of pain.

While symptomatic assessment is important, if not essential, to diagnose syndrome expression accurately within this spectrum disorder, and ultimately determine the best type(s) of care, it is equally important to attempt to identify the underlying causes that may reflect particular syndromes or subsyndromes of the TSR continuum. As such, the current authors hypothesize that the effects of mind-brain injury are approached better by assessing the full spectrum of trauma-related morbidities and treating the whole person rather than dividing a patient's morbidities into subcomponents and treating symptom by symptom⁹³; to be maximally effective in managing the complexity of wrTSR, both presenting symptoms and underlying constitutional vitality should be addressed simultaneously.

In the design of the study protocol, the current authors hypothesize that both acupuncture methods will improve headache-related QoL and reduce headache severity and frequency over the 6-week study period, compared to a usual care (UC) group. Furthermore, because the theoretical underpinnings of TCA are grounded in treating underlying constitution, and this protocol has been specifically designed to address comorbid symptoms, it is expected that this approach will be more effective for reducing comorbid symptoms (the full wrTSR), compared to AA and UC groups.

METHODOLOGY

Study Design

The research study design is a three-armed (TCA, AA, and UC control) randomized, controlled, exploratory 12-week study in active duty military personnel diagnosed with TBI and headache (Fig. 1). Study participants randomized to either of the two acupuncture groups will receive ten acupuncture treatments over 6 weeks. During the course of the 6 weeks, all study participants, regardless of randomization assignment, will complete a daily headache diary and con-

tinue to receive usual standard care for TBI, headache, and other comorbid symptoms as currently provided by their health care providers. Outcome measures will be collected at baseline, week 6, and week 12.

The study protocol, informed consent, and HIPAA form were approved by the Walter Reed Army Medical Center (WRAMC) Human Use Committee, the Clinical Investigation Regulatory Office (CIRO), and the USAMRMC Office of Research Protections Human Research Protections Office (ORP HRPO).

Study Eligibility and Exclusion Criteria

The inclusion criteria were selected to recruit and enroll a cohort with mild-to-moderate TBI, based on the current protocol used at WRAMC and the standard Department of Defense/Department of Veterans Affairs (DoD/DVA) TBI definition.

Service members between ages of 18 and 69 who had previously been deployed to a war zone, sustained mild-to-moderate TBI, and have current headaches of any etiology are eligible for study enrollment. A requirement of at least 4 headache days per month requiring any use of prescription or over-the-counter treatment has been included to maximize recruitment of patients significantly affected by chronic headaches. Furthermore, participants must have sufficient cognitive function to provide informed consent with Rancho Los Amigos Cognitive Scale (RLACS) scores of ≥ 7 . Exclusion criteria include acupuncture treatment within the past month; any unstable medical, psychiatric, or surgical condition that might warrant inpatient treatment; and females who are currently pregnant or lactating.

Screening Process

Potential participants who learn about the study through institutional review board (IRB)-approved advertisements or who are referred from the TBI clinic are screened by a research staff member by phone. Those who meet initial criteria and voice an interest in participation then sign a release of medical information so that relevant medical records can be reviewed to verify eligibility. A screening log with all potential study participants has been stored on a double-password protected HIPAA Sharepoint site.

Baseline Assessment and Informed Consent Process

Potential participants who meet all eligibility criteria are then scheduled for a baseline appointment to receive a detailed explanation of the study, review the informed consent and HIPAA forms with a civilian research team member, have any questions answered, and, if interested, sign informed consent. Research staff then administer the study outcome measures, review the headache diary, and schedule an initial assessment with the lead study acupuncturist. On

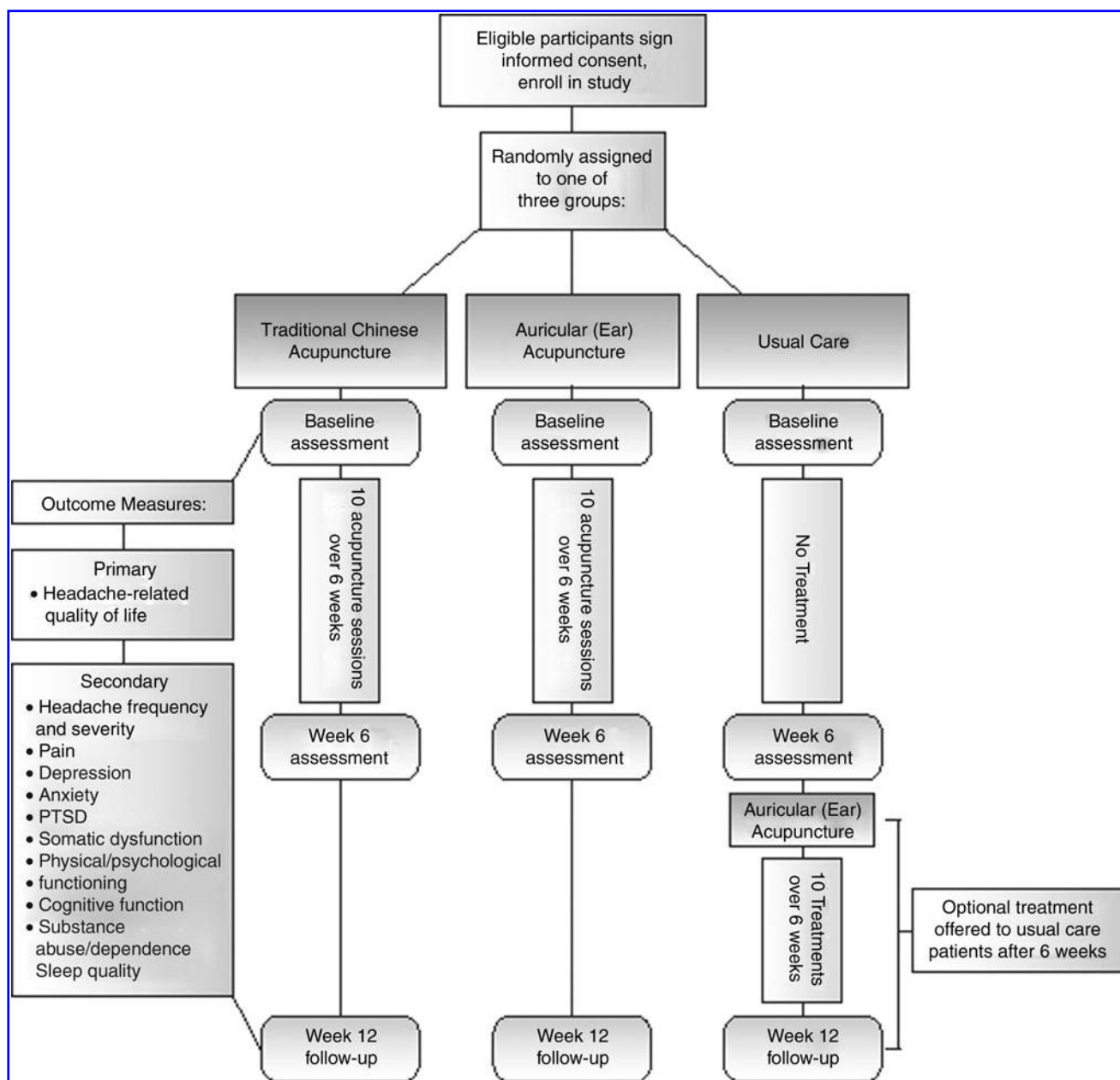


FIG. 1. Study design. PTSD, post-traumatic stress disorder.

an ongoing basis, research study staff coordinate with each participant's nurse case manager to ensure that Command is aware of their participation in the study.

Study Acupuncturists

All acupuncture treatments are administered by two licensed acupuncturists with Master's Degrees in Acupuncture from the Tai Sophia Institute, Maryland state licensure, and WRAMC credentialing. Both acupuncturists possess extensive clinical experience, expertise in Traditional Chinese diagnosis and treatment of chronic headaches

and trauma. Both also received training by U.S. Air Force Col. Richard C. Niemtow (developer of this particular AA approach) in the ear acupuncture protocol and have demonstrated proficiency in administering this procedure.

Initial Clinical Assessment and Randomization

The lead acupuncturist conducts a 90-minute initial clinical assessment on all study participants to determine each individual's: (1) primary and secondary headache patterns based on TCM diagnostic skills of pulse reading, tongue diagnosis, history, and assessment of signs and

symptoms; (2) underlying constitutional imbalances, using the 5-Element model; and (3) local painful points known as Ah-Shi points. This assessment allows for a standardized approach to individualized treatment, including a standard selection of points to be used for each headache pattern, for treating constitution and Ah-Shi points.

Enrolled study participants are randomized to one of three groups (AA, TCA, or UC) by research staff, using a list randomizer (www.random.org), which generates a list of 90 treatment allocations with 30 participants randomly assigned to each group. A research associate records the assignment of each participant in a confidential log stored on a double-password protected HIPAA Sharepoint site. At the end of the acupuncturist's initial assessment, a research coordinator contacts the lead acupuncturist to inform her and the study participants of the randomization result. If randomized to an intervention group, study participants may opt to receive the first treatment at this time or schedule another treatment time. If randomized to the UC group, participants are asked to continue their current treatment regimens.

INTERVENTIONS

Approach to Offering Acupuncture: Facilitating a Healing Context

An important aspect of each patient interaction is to facilitate a healing environment that addresses the concerns of individuals with traumatic stress. Study acupuncturists consistently deliver the same approach to all study participants (regardless of treatment assignment) in order to assist individuals in orienting themselves to the present moment and feeling a sense of control and empowerment. To bring attention and awareness to the healing process, patients are (1) given time to orient themselves to the room, (2) given control of when needles are inserted, and (3) are asked to track pain levels before and after treatment allowing them to somatically mark and harvest a change in pain levels.

TCA Protocol

The semi-individualized TCA procedure is based on an approach developed by Dr. Michael Hollifield, Elaine Duncan, and a team of acupuncturists, that was based, in part, on an approach that was found to be effective for treating PTSD.⁷⁰ This approach uses a semi-standardized acupuncture technique that was carefully developed from TCA and matched to the wrTSR syndrome. The technique describes features of PTSD and other comorbidities in terms of TCM patterns and then allows a limited range of individual acupuncture points to be used.

Based on the initial clinical assessment, the lead study acupuncturist develops an individualized acupuncture treatment plan for each study participant randomized to the

TCA group. This includes the administration of acupuncture needles to (1) up to 3 pairs of points associated with the primary headache pattern, (2) up to 2 pairs of points associated with the secondary headache pattern, (3) up to 4 Ah-Shi points, and (4) the source points on the 2 meridians associated with their constitution plus up to 2 pairs of additional points from a selected list. Thus, up to 22 acupuncture points may be needled at any given 60-minute treatment session. While the majority of points are on the limbs, points also include local points of tenderness of the head, and the front and back of the torso. Point selection is reassessed every 2 weeks per TCM diagnostic and treatment principles.

Auricular Acupuncture Protocol

The ear acupuncture technique for this study was developed and has been used clinically by Col. Niemtow, a medical acupuncturist, in the Acupuncture Clinic at Andrews Air Force Base, MD. This procedure has been extensively used in Col. Niemtow's practice, and studies using a similar ear acupuncture intervention in military cohorts demonstrated that it was effective in reducing acute pain as well as chronic, refractory pain.²⁴ Each ear session lasts approximately 45 minutes and includes the insertion of needles into the outer ear using the following algorithmic procedure.

A combination of Seirin and gold ASP needles are used to needle 5 ear points and 1 scalp point in an algorithmic approach depending on whether the patient initially presents with a headache, and whether that headache persists after needling. Treatment begins using Seirin needles, and patients are sent home with indwelling ASP needles at the end of each session. Depending on an individual's response after each set of needles is inserted (i.e., a decrease or persistence of headache pain on a 10-point Likert scale), anywhere from 6 to 9 points may be needled during each treatment session.

Usual Care

A detailed guideline describes the assessment, clinical algorithms, and pharmacologic treatment guidelines for the management of TBI-related symptoms;⁹⁴ TBI-associated headaches are treated preventively with a combination of antidepressants, antiepileptics, and beta-blockers; abortive management of episodic headaches includes treatment with nonsteroidal anti-inflammatory drugs, tryptans, combination medications, and other nonmedication treatment options such as physical therapy. As this is the standard of care for patients with TBI, this guidance will encompass the UC regimen for all study participants.

The UC group members continue with their current treatment regimens and complete the headache diary. After 6 weeks, these patients are given the option to receive 10 ear acupuncture treatments over a 6-week period.

OUTCOME MEASURES

Primary and secondary outcome measures are obtained at three time points: baseline, week 6 (after completion of acupuncture treatments or wait period), and a follow-up at week 12.

Primary Outcome Measure: Headache-Related QoL

The Headache Impact Test (HIT) is a reliable and valid measure in heterogeneous populations of headache sufferers.⁴⁷ It is a six-item questionnaire that assesses an individual's perception of headache burden over the past month. Scores range from 36 to 78; HIT scores > 59 are consistent with severe impairment in headache-related QoL.

Secondary Outcome Measures

Secondary outcomes include measures of headache frequency and severity, and TBI-associated wrTSD comorbidities, including pain, depression, anxiety, PTSD symptoms, somatic dysfunction/physical functioning, cognitive function, and sleep quality.

STUDY STATUS

As of July 2011, 15 participants have consented and enrolled in the study. Of the 5 subjects currently in the study, 4 have been randomized to UC and 1 to TCA. Six participants (TCA, $n=3$; AA, $n=2$; Usual Care, $n=1$) have completed the study. Four chose to withdraw their consent for various reasons, including scheduling conflicts ($n=3$) and medical issues ($n=1$).

In November of 2005, the Base Closure and Realignment Commission (BRAC) designated the closure of WRAMC, which will then be incorporated with the National Naval Medical Center to become the Walter Reed National Military Medical Center (WRNMMC) in Bethesda, MD. Subsequently, enrollment of participants will resume once the protocol has been approved by the WRNMMC IRB.

DISCUSSION

As discussed in the Introduction, current evidence from acupuncture research demonstrates a ubiquitous healing impact across the trauma spectrum response. The same or similar approaches seem to reduce pain, depression, sleep and energy problems, anxiety, and PTSD symptoms, and lessen dependency or drug use. The many mechanisms through which acupuncture works seem to induce a widespread healing response that may reset the traumatized individual across the spectrum. Thus, the potential for acupuncture to have deep and lasting impact across a number of conditions—producing a true healing effect—is promising. There are, however, a number of unanswered

questions, information gaps, and challenges to capitalizing on this potential. First is the question of how much of the effects of acupuncture are nonspecific—that is, a result of the context, process, ritual, and other placebo components of acupuncture delivery. If the major impact of acupuncture is not strongly linked to the specific points needed to produce the effects, then advancing major training programs teaching specific point locations may not be needed and a simple technique, as is being done in the AA arm of this study, could be sufficient. Yet, if maximizing the ritual to provide the greatest benefit to patients is desired, full training in the ritual and point location, as described in the TCA section of this protocol, is required. This study should advance understanding of the speed and depth of healing induced by these two approaches and compare it to current practice.

The above information is critical for deciding if and how to implement acupuncture in the rest of the military. The most widespread delivery of acupuncture could be achieved if existing military workforce positions, including medics, nurses, physician assistants, physical therapists, etc., were used. This might be best done both inside and outside the context of mental health services and so serve persons better who avoid mental health care because of stigma. Acupuncture treatment of wrTSR might be ideal for helping these SMs if delivered by ancillary and non-mental health personnel, perhaps in the field, on ships, or in primary care clinics as adjunctive care. Delivery of acupuncture in these settings, however, would require extensive training programs not currently available or standardized for delivery in the rest of the military. Standardization would control the quality of delivery but might not provide the full benefit if the ritual effects of acupuncture practice were reduced to the more easily teachable components of point location and formula protocols. In addition, personnel not directly involved in acupuncture treatment (i.e., clinic and hospital commanders, other members of the pain care team) might not understand or value the unique issues around acupuncture delivery and could also undermine its full utility if they deal with it the same way they might use a drug or transcutaneous electrical nerve stimulation unit for example, slotting only 10–15 minutes for a procedure. Even after the extensive discussion of this protocol by military leaders on the need for pragmatic studies, many of the reviewers of the protocol, both after the grant submission and during the IRB review, failed to understand or agree with the CER approach. The chaotic processes around scientific and IRB review threaten the ability of DoD leadership to obtain crucial information about acupuncture, which, in turn, prevents delivery of what may be a widely effective approach for service members with wrTSR.

CONCLUSIONS

These challenges can be addressed. Acupuncture and other whole-person healing approaches are relatively

simple, drugless, stigma-free, and popular with the public. They may offer ways to heal the response to trauma on a widespread basis if we can determine the best way to deliver them. As the wars wind down, we will surely need more and improved tools for the alleviation of the suffering they have produced.

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